UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Offic
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/489,101	01/21/00	GURE A	L0461/7073(J

HM12/0424

John R Van Amsterdam
Wolf Greenfield & Sacks PC
600 Atlantic Avenue
Boston MA 02210

EXAMINER	
PENN,M	
ART UNIT	**PAPER NUMBER**
1633	8

DATE MAILED: 04/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/489,101	GURE ET AL.	
	Examiner	Art Unit	
	Michael G. Penn	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7,16,50,52,63,65,70-72,78-80,85,88,98,102,109 and 115* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1,2,7,16,50,52,63,65,70-72,78-80,85,88,98,102,109 and 115* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 2, drawn to a method of diagnosing a disorder characterized by expression of a human cancer associated antigen precursor using an agent that is a nucleic acid molecule o group 1, 3, or 5, classified in class 435, subclass 6.

II. Claims 1 and 2 drawn to a method of diagnosing a disorder characterized by expression of a human cancer associated antigen precursor using an agent that binds to a nucleic acid molecule expression product, classified in class 435, subclass 7.1+.

III. Claims 1,2, and 115, drawn to a method of diagnosing a disorder characterized by expression of a human cancer associated antigen precursor using an agent that is an antibody, classified in class 435, subclass 7.1+.

IV. Claim 7, drawn to a method for determining regression, progression, or onset of a condition characterized by expression of abnormal levels of a protein encoded by a nucleic acid molecule that is a NA Group I molecule comprising monitoring a patient sample for a protein or peptide, classified in class 435, subclass 7.1+.

V. Claim 7, drawn to a method for determining regression, progression, or onset of a condition characterized by expression of abnormal levels of a protein encoded by a nucleic acid molecule that is a NA Group I molecule comprising monitoring a patient sample for an antibody which selectively binds the protein or peptide, classified in class 435, subclass 7.1+.

VI. Claim 7, drawn to a method for determining regression, progression, or onset of a condition characterized by expression of abnormal levels of a protein encoded by a nucleic acid molecule that is a NA Group I molecule comprising monitoring a patient sample for cytolytic T cells specific for a complex of the peptide derived from the protein and an MHC molecule, classified in class 435, subclass 7.1+.

VII. Claims 16, 78-80, 98, drawn to a method of treatment using an agent and pharmaceutical compositions thereof, classified as unclassifiable.

VIII. Claims 50, 52, 70-72, drawn to Group 1 and Group 2 polypeptides, isolated fragments, and pharmaceutical compositions thereof, classified in class 424, subclass 277.1.

IX. Claims 63, 65, drawn to an expression vector comprising Group 1 or Group 2 nucleic acids and a nucleic acid encoding an HLA molecule, and host cells, classified in class 435, subclass 320.1 and 325.

X. Claim 85, drawn to a method of treatment using cytolytic T cells, classified in class 435, subclass 2.

XI. Claim 88, drawn to a method of treatment using transfected host cells, classified in class 435, subclass 455+.

XII. Claim 102, drawn to a method of treatment using isolated T cells, classified in class 435, subclass 2.

XIII. Claim 109, drawn to a composition useful in stimulating an immune response to proteins encoded by Group 1 nucleic acids, comprising peptides derived from the proteins, classified in class 424, subclass 277.1.

Claims 1 and 2 link(s) inventions I, II, and III, and claim 7 links inventions IV, V, and VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1, 2, and 7. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, and III are patentably distinct, each from the other, because although drawn to methods of diagnosing a disorder characterized by expression of a human cancer associated antigen precursor, Invention I uses an agent that is a nucleic acid, Invention II uses an agent that binds to a nucleic acid expression product, and Invention III uses an agent that is an antibody. Different methods and reagents are necessary to practice each of these inventions. For example, generation of a nucleic acid probe that hybridizes to a desired nucleic acid sequence involves completely different methods and reagents than generating an antibody to a protein. Moreover, a divergent search would be required to examine each of these inventions, therefore restriction is proper.

Inventions IV, V, and VI are patentably distinct, each from the other, because although drawn to methods for determining regression, progression, or onset of a condition characterized by expression of abnormal levels of a protein encoded by a nucleic acid molecule that is a NA Group I molecule, Invention IV involves monitoring a patient sample for a protein or peptide, Invention V involves monitoring a patient sample for an antibody, and Invention VI involves monitoring a patient sample for a specific CTL. Different methods and reagents are necessary to practice each of these inventions. Furthermore, a divergent search would be required to examine each of these inventions, therefore restriction is proper.

Inventions I-III are patentably distinct from Inventions IV-VI because Inventions I-III are directed to a method for diagnosing a disorder, whereas Inventions IV-VI are

directed to a method for following the progress of a disease. Different methods and reagents are necessary to practice each of these inventions. For example, the required sensitivity of an assay for tracking the progress of a disease may vary greatly from that required to diagnose it, since as the disease progresses the target of detection may have quite varying expression levels. Moreover, as the disease progresses, different forms of the target of detection may appear, thus requiring different reagents to detect it. Therefore, restriction is proper.

Inventions VII, X, XI, and XIII are patentably distinct, each from the other, because although drawn to methods of treating a disorder, Invention VII uses an unspecified agent that enriches the presence of HLA molecules and cancer associated antigen, Invention X uses *in vitro* stimulated cytolytic T cells, Invention XI uses transfected host cells, and Invention XII uses isolated T cells. Different methods and reagents are necessary to practice each of these inventions. For example, transfecting host cells requires optimization of and subsequent performance of gene therapy protocols to transfect the cell, while using isolated T cells requires identification of the desired T cell clone, in vitro expansion, and finally delivery of the proper dose. Additionally, divergent fields of search are required for each of these inventions, therefore restriction is proper.

Inventions I-VI are patentably distinct from Inventions VII, and X-XII because Inventions I-VI are directed to methods of diagnosing or monitoring a disorder, whereas Inventions VII, X-XII are directed to methods of treating a disorder using CTL's, transfected host cells, or an unspecified agent. The protocols and reagents necessary

to practice a treatment of a disorder are wholly different than those required to diagnose or monitor a disorder, additionally requiring divergent fields of search, therefore restriction is proper.

Inventions I-VI are patentably distinct from Invention VIII because Inventions I-VI are directed to methods of diagnosing or monitoring a disorder, whereas Invention VIII is directed to pharmaceutical compositions of Group 1 or Group 2 polypeptides. The methods of Inventions I-VI are not required for Invention VIII. Furthermore, a divergent search would be required to examine compositions of polypeptides and also methods of diagnosing a disorder, therefore restriction is proper.

Inventions I-VI are patentably distinct from Invention IX because Inventions I-VI are directed to methods of diagnosing or monitoring a disorder, whereas Invention IX is directed to an expression vector comprising Group 1 or Group 2 nucleic acids, and a nucleic acid encoding an HLA molecule. The methods and reagents of Inventions I-VI are not required for Invention IX. Furthermore, a divergent search would be required to examine expression vectors and also methods of diagnosing a disorder, therefore restriction is proper.

Inventions I-VI are patentably distinct from Invention XIII because Inventions I-VI are directed to methods of diagnosing or monitoring a disorder, whereas Invention XIII is directed to a composition of peptides useful in stimulating an immune response. The methods and reagents of Inventions I-VI are not required for Invention IX. Furthermore, a divergent search would be required to examine peptides that stimulate an immune response and also methods of diagnosing a disorder, therefore restriction is proper.

Inventions VII and X-XII are patentably distinct from Invention VIII because Inventions VII, X-XII are directed to methods of treating a disorder using CTL's, transfected host cells, or an unspecified agent, whereas Invention VIII is directed to pharmaceutical compositions of Group 1 or Group 2 polypeptides. The methods and reagents of Inventions VII and X-XII are not required for Invention VIII. Furthermore, a divergent search would be required to examine these inventions, therefore restriction is proper.

Inventions VII and X-XII are patentably distinct from Invention IX because Inventions VII, X-XII are directed to methods of treating a disorder using CTL's, transfected host cells, or an unspecified agent, whereas Invention IX is directed to an expression vector comprising Group 1 or Group 2 nucleic acids, and a nucleic acid encoding an HLA molecule. The methods and reagents of Inventions VII and X-XII are not required for Invention IX. Furthermore, a divergent search would be required to examine these inventions, therefore restriction is proper.

Inventions VII and X-XII are patentably distinct from Invention XIII because Inventions VII, X-XII are directed to methods of treating a disorder using CTL's, transfected host cells, or an unspecified agent, whereas Invention XIII is directed to a composition of peptides useful in stimulating an immune response. The methods and reagents of Inventions VII and X-XII are not required for Invention XIII. Furthermore, a divergent search would be required to examine these inventions, therefore restriction is proper.

Invention VIII is patentably distinct from Invention IX because Invention VIII is directed to pharmaceutical compositions of Group 1 or Group 2 polypeptides, whereas Invention IX is directed to an expression vector comprising Group 1 or Group 2 nucleic acids, and a nucleic acid encoding an HLA molecule. The methods and reagents of Invention VIII are not required for Invention IX. Furthermore, a divergent search would be required to examine these inventions, therefore restriction is proper.

Invention VIII is patentably distinct from Invention XIII because Invention VIII is directed to pharmaceutical compositions of Group 1 or Group 2 polypeptides, whereas Invention XIII is directed to a composition of peptides useful in stimulating an immune response. The methods and reagents of Invention VIII are not required for Invention XIII. Furthermore, a divergent search would be required to examine these inventions, therefore restriction is proper.

Invention IX is patentably distinct from Invention XIII because Invention IX is directed to an expression vector comprising Group 1 or Group 2 nucleic acids, and a nucleic acid encoding an HLA molecule, whereas Invention XIII is directed to a composition of peptides useful in stimulating an immune response. The methods and reagents of Invention IX are not required for Invention XIII. Furthermore, a divergent search would be required to examine these inventions, therefore restriction is proper.

Note further that this application contains claims directed to patentably distinct species of the claimed inventions.

Should applicant elect Invention I, II, or III, applicant is further required to elect a species from the following:

a. group 1 nucleic acid molecules
b. group 3 nucleic acid molecules
c. group 5 nucleic acid molecules
d. an antibody that binds to the expression product of group 1 nucleic acid molecules
e. an antibody that binds to the expression product of group 3 nucleic acid molecules
f. an antibody that binds to the expression product of group 5 nucleic acid molecules
g. an agent that binds to a complex of an HLA molecule and a fragment of an expression product of a group 1 nucleic acid
h. an agent that binds to a complex of an HLA molecule and a fragment of an expression product of a group 3 nucleic acid
i. an agent that binds to a complex of an HLA molecule and a fragment of an expression product of a group 5 nucleic acid

Should applicant elect Invention VIII, applicant is further required to elect a species from the following:

a. Group 1 polypeptide
b. Group 2 polypeptide

Should applicant elect Invention IX, applicant is further required to elect a species from the following:

a. Group 1 nucleic acids and a nucleic acid encoding an HLA polypeptide
b. Group 2 nucleic acids and a nucleic acid encoding an HLA polypeptide

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 7, 50, 63, and 85 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Penn who can normally be reached on Monday through Friday from 8:00 am to 4:30 p.m. at (703) 308-2454.

Questions of formal matters can be directed to the patent analyst, Kimberly Davis, who can normally be reached on Monday through Friday from 9:00 am to 5:30 p.m. at (703) 305-3015.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael G. Penn

Deborah Clark

DEBORAH J. R. CLARK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600